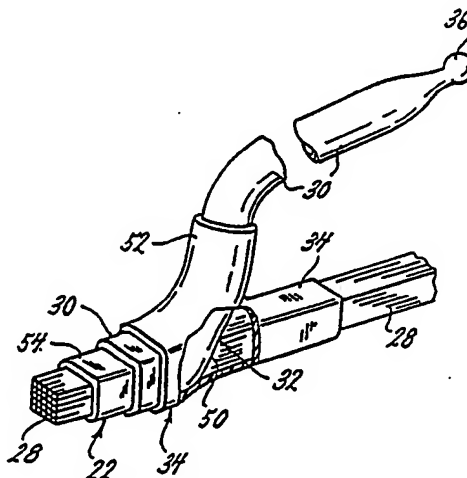




## INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification 5 : <b>G02B 23/26</b>		A1	(11) International Publication Number: <b>WO 91/15793</b> (43) International Publication Date: <b>17 October 1991 (17.10.91)</b>
(21) International Application Number: <b>PCT/US91/02404</b> (22) International Filing Date: <b>10 April 1991 (10.04.91)</b> (30) Priority data: 508,899 11 April 1990 (11.04.90) US 600,206 18 October 1990 (18.10.90) US 680,756 9 April 1991 (09.04.91) US (71) Applicants: <b>WASHINGTON UNIVERSITY [US/US];</b> One Brookings Drive, St. Louis, MO 63130 (US). <b>FIBER</b> <b>IMAGING, INC. [US/US];</b> 500 S. Ewing, Suite A, St. Louis, MO 63103 (US). (72) Inventors: <b>ACCSTA, George, M. ;</b> 1467 Dietrich Oaks Drive, Manchester, MO 63021 (US). <b>BINNS, W., Robert</b> ; 11128 Queensway, St. Louis, MO 63146 (US). <b>EP-</b> <b>STEIN, John, W. ;</b> 7218 Clayton Road, St. Louis, MO 63117 (US).		(74) Agent: <b>HAFERKAMP, Richard, E.;</b> Rogers, Howell & Haferkamp, 7777 Bonhomme, Suite 1700, St. Louis, MO 63105 (US). (81) Designated States: <b>AT</b> (European patent), <b>AU, BB, BE</b> (European patent), <b>BF</b> (OAPI patent), <b>BG, BJ</b> (OAPI patent), <b>BR, CA, CF</b> (OAPI patent), <b>CG</b> (OAPI patent), <b>CH</b> (European patent), <b>CM</b> (OAPI patent), <b>DE</b> (Euro- pean patent), <b>DK, DK</b> (European patent), <b>ES</b> (European patent), <b>FI, FR</b> (European patent), <b>GA</b> (OAPI patent), <b>GB</b> (European patent), <b>GR</b> (European patent), <b>HU, IT</b> (European patent), <b>JP, KP, KR, LK, LU</b> (European pa- tent), <b>MC, MG, ML</b> (OAPI patent), <b>MR</b> (OAPI patent), <b>MW, NL</b> (European patent), <b>NO, PL, RO, SD, SE</b> (Eu- ropean patent), <b>SN</b> (OAPI patent), <b>SU, TD</b> (OAPI pa- tent), <b>TG</b> (OAPI patent).  <b>Published</b> <i>With international search report.</i>	

(54) Title: ENDOSCOPE WITH SINGLE PLASTIC FIBER OPTIC BUNDLE



## (57) Abstract

An endoscope (20) is disclosed which incorporates a plastic multi-fiber optic bundle assembly (22) for both illuminating and imaging tissue specimens. The bundle assembly (22) is comprised of a plastic multi-fiber optic bundle (28) surrounded by an individually cladded plastic optical fiber (30), with the bundle assembly (22) having a cross-section matching that of a single opening (24) extending through the length of the catheter (26) to thereby minimize the cross-sectional area of the catheter itself and optimize its flexibility. A multi-fiber optical bundle (28) used for imaging and apparatus and methods for forming the bundle (28) with arrays of individually cladded fibers (30) is disclosed. Several embodiments are disclosed of varying geometrical arrangements. An alternative embodiment is disclosed wherein a square multi-fiber imaging bundle (78) and four round illuminating fibers (80) are inserted through a generally circular opening (24) in the catheter (26). In still another embodiment, a mirror (86) or beam splitter (92) may be used to transmit illuminating as well as imaging light through a single multi-fiber bundle (84). In still another embodiment, a multi-fiber annular shaped guide (100) is used to transmit the illuminating light, and a method for forming it from a plurality of individually cladded plastic fibers (102) is disclosed.

**FOR THE PURPOSES OF INFORMATION ONLY**

Codes used to identify States party to the PCT on the front pages of pamphlets publishing international applications under the PCT.

AT	Austria	ES	Spain	MG	Madagascar
AU	Australia	FI	Finland	ML	Mali
BB	Barbados	FR	France	MN	Mongolia
BE	Belgium	GA	Gabon	MR	Mauritania
BF	Burkina Faso	GB	United Kingdom	MW	Malawi
BG	Bulgaria	GN	Guinea	NL	Netherlands
BJ	Benin	GR	Greece	NO	Norway
BR	Brazil	HU	Hungary	PL	Poland
CA	Canada	IT	Italy	RO	Romania
CF	Central African Republic	JP	Japan	SD	Sudan
CG	Congo	KP	Democratic People's Republic of Korea	SE	Sweden
CH	Switzerland	KR	Republic of Korea	SN	Senegal
CI	Côte d'Ivoire	LI	Liechtenstein	SU	Soviet Union
CM	Cameroon	LK	Sri Lanka	TD	Chad
CS	Czechoslovakia	LU	Luxembourg	TC	Togo
DE	Germany	MC	Monaco	US	United States of America
DK	Denmark				

-1-

ENDOSCOPE WITH SINGLE PLASTIC FIBER OPTIC BUNDLE10 Background and Summary of the Invention

Endoscopes are well known in the art as devices for insertion into a patient's body to enable a physical examination of tissue contained therein. Generally, an endoscope includes a light source, optics, means for  
15 transmitting the incident light from the light source to the tissue, means for collecting and transmitting light

returning from the tissue back to the physician's eye, and optics to reconstruct an image of the tissue from the returning light. Additionally, an endoscope may have a working channel which permits a physician to take tissue samples, flush the tissue site with saline, or otherwise physically contact the tissue being examined. This working channel as well as the light transmitting and viewing means is bundled into a catheter with the catheter being of some appreciable length, normally about a meter.

The design criteria for the catheter of a disposable endoscope include maximum flexibility, minimal cross-sectional area, and minimal cost. With the present day environment of highly contagious and deadly diseases, such as AIDS, there is a growing reluctance in the medical community to sterilize and reuse any medical devices which come in contact with bodily fluids, including especially blood. Thus, as the endoscope almost inevitably comes into contact with blood and certainly comes into contact with bodily fluids, there is a growing demand for a disposable endoscope. While there have been significant advances in the area of optic fibers for endoscopes, the prior art does not indicate that others have been successful in designing and developing reduced cost, plastic fiber optics which demonstrate adequate light transmissibility and resolution in a size sufficiently small for effective use in an endoscope.

One such attempt of the prior art is shown in U.S. Patent No. 4,872,740 which discloses an endoscope utilizing a multi-filament type plastic optical fiber for transmitting the image of the tissue being examined. However, this multi-filament type plastic optical fiber is constructed in an islands-in-sea structure in which 50 to 10,000 sheathed light transmitting fibers (islands) are separately formed and then arranged in a bundle bound together with an appropriate cladding material (sea). This structure does result in a multi-filament type plas-

tic optical fiber for imaging, however, it is believed that significant cost and several manufacturing steps are required in order to achieve it. Additionally, the packing of the fibers is not as dense as possible, there  
5 being interstices between adjacent fibers. Furthermore, the patent teaches the use of a separate fiber bundle for transmission of incident light through the catheter for illuminating the tissue to be examined. There is no disclosure or suggestion of any technique or structure  
10 for combining these separate bundles or even their geometry with respect to the catheter.

Still another prior art patent of some interest is U.S. Patent No. 4,736,733. In that patent, an endoscope is disclosed utilizing a catheter having a central, generally round, coherent fiber bundle for imaging, which is  
15 surrounded by a number of individual optical fibers to transmit the incident light. While this patent does make an attempt to address the inherent space limitation problem in a catheter, it unfortunately adds an extra layer of material, which is the tubular outer covering required  
20 to hold the multiple incident light fibers in place around the imaging fiber.

Still another prior art patent of some interest is U.S. Patent No. 4,648,892. In this patent there is disclosed a catheter which, in several of the embodiments,  
25 utilizes the same, single fiber for transmission of the incident and reflected light. However, the incident light utilized in the '892 patent is a laser (preferably) such that it is suggested for use with a single optical  
30 fiber and not a fiber bundle.

The disclosure does not concern itself with the use of multiple fibers, except to suggest that stepper motors, computers, and other controllers of the like may be used to separately access individual fibers of a fiber  
35 bundle. While these techniques are useful with a laser as the incident light source, such techniques fail with

conventional light sources due to its lessened intensity. Furthermore, the '892 patent does not address itself to problems inherent in utilizing the plastic fibers generally considered to be more suited to a disposable endoscope.

In addition to those patents mentioned above, still other prior art discloses endoscopes utilizing glass multi-filament optical fibers for the imaging bundle and/or the illuminating fiber. In some prior patents, the illuminating fiber is disclosed as surrounding the imaging fiber. However, glass optical fibers suffer from the disadvantages of cost, undesired inflexibility, and susceptibility to breakage which minimizes their usefulness in fashioning a low-cost disposable endoscope.

In order to solve these and other problems in the prior art, the inventors herein have succeeded in designing and developing a low-cost, disposable, endoscope which, in its various embodiments, utilizes one of several assemblies of plastic, multi-fiber optic imaging bundles which are constructed in accordance with the teachings herein. As disclosed in greater detail below, a plastic, multi-fiber optic bundle of reduced size may be constructed of individual members which are themselves multi-fiber bundles, and the process can be taken to even a third step such that the end product is a "bundle of bundles of bundles" to provide a fiber having more than 14,000 pixels, each pixel being an individually clad plastic optical fiber, which dramatically increases its light transmissibility and resolution.

In an alternative embodiment, the primary preform may be used to create a continuous fiber of reduced size which is wrapped around a wheel as it is formed and a process for aligning the fibers, forming them into arrays, and then fusing them for a second draw is disclosed. With this alternative methodology, only two

draws of the fibers need be made in order to achieve fiber sizes and bundle sizes in the range required for the endoscope application disclosed and claimed herein. For example, it is anticipated that imaging bundles of approximately .5 mm on a side, having a square cross-sectional shape, will be used. Each imaging bundle shall have approximately 6,000 individual fibers or pixels, each fiber having a width of approximately 6.4 microns of which 1.07 microns is clad thickness and 4.3 microns is core thickness.

A process is disclosed for making the individual fibers which are then used to fabricate the multi-fiber imaging bundles. In this process, a distillation step is disclosed for distilling the raw material used to form the core. This process eliminates the inhibitor normally present in commercial grade styrene monomer which might otherwise interfere with the fusing steps used to work the fiber. Additionally, distillation removes virtually all of the impurities of the commercial plastic product forming the core and thereby dramatically improves the light transmissibility of the finished fiber. In another novel process, the purified raw material for the core is polymerized into a billet or preform which is then inserted within a preform of cladding material. The core and cladding are then fused and drawn to form the primary fibers used in a second or even a third draw to create the reduced size fibers necessary for the endoscope application disclosed herein.

Using the processes and techniques disclosed herein, and especially wherein a preform is constructed by fusing a hollow tube of cladding to a central core, fibers having virtually any crosssectional shape may be made. For example, in a preferred embodiment, square fibers are constructed which lend themselves to being packed in an orthogonal array with no interstices between adjacent fibers. In many of the prior art patents known

to the inventors, fibers having a generally circular cross-sectional area are formed with conventional prior art techniques. Of course, fibers having a circular cross-sectional area have wasted space between adjacent fibers which can be significant in a multi-fiber construction. Thus, fibers having a cross-sectional shape of a regular polygon enhance the performance of multi-fibers wherein every bit of cross-sectional area becomes important in striking a balance between the competing desirable attributes of pixel quantity versus pixel size. This is especially true as fibers are constructed which push the limit of minimum cladding thickness and/or clad-to-core ratios. Wasted space in the interstices between adjacent fibers is not seen to add significantly to any of the useful measures of fiber performance. Thus, it is desired to minimize or eliminate these interstices as is achieved with fibers having regular polygon cross-sectional shapes made in accordance with the teachings herein. This, combined with the other features of the process disclosed herein, enables the use of a plastic, multi-fiber optic bundle comprised of a plurality of individually cladded, closely packed optical fibers as the imaging fiber.

This imaging fiber may then be encapsulated in a surrounding cladded plastic optical fiber which can be used for transmitting the incident light. Thus, incident light may be transmitted along the periphery of the fiber assembly to the distal end of the endoscope, while imaging or returning light is transmitted back to the proximal end through the central multi-fiber bundle. With this embodiment, a single plastic fiber optic bundle assembly, consisting of a multi-fiber bundle within a second cladded fiber, having a reduced cross-sectional area may be utilized in the catheter which minimizes the cross-sectional area of the catheter to provide increased flexibility over glass fibers at greatly reduced cost.



The fiber optic bundle assembly can be constructed utilizing a variety of geometries, as is explained in greater detail below, and the fibers may even be tapered to further reduce the cross-sectional area extending through the catheter.

In still another embodiment utilizing the cladded plastic, multi-fiber optic bundle alone without the separate surrounding fiber, an arrangement is disclosed wherein the incident light may be directed through a predetermined portion, or pre-selected ones of the fibers, of the multi-fiber bundle and the balance of the bundle used to transmit returning light for imaging the tissue being examined. Alternatively, a beam splitter may be used to direct the incident light across the entire face of the multi-fiber bundle with the returning light carrying the image of the tissue also being transmitted through the entire cross-sectional area of the bundle. In this alternative embodiment, the entire multifiber bundle serves to transmit both incident light for illumination and returning light for imaging.

In still another embodiment, the multi-fiber imaging bundle is surrounded by an illuminating fiber which is itself comprised of a plurality of cladded plastic optical fibers fused into a tube-like structure. This multi-fiber illuminating guide provides significant advantages over prior art illuminating fibers including improved light transmissibility and hence brightness at the tissue site, improved uniformity of illumination, and greatly improved flexibility over single optical fibers or plastic sleeves. This multi-fiber illuminating guide may be formed in a ring one fiber thick, or it may have multiple rows of thickness. In the embodiment with multiple rows, a gradient in the illuminating light may be created either with scintillating fibers which produce different hues or intensities, or with a gradient light source selectively coupled to the appropriate rows. In

still another embodiment, multi-fiber construction can be used to form the individual fiber members of the illuminating guide, thereby providing enhanced illumination both in brightness and uniformity through the substantially increased number of pixels.

Also disclosed is a mandrel and tube for assembling the individual fibers, and a process for fusing these fibers into the annular-shaped illuminating fiber guide. With this process, the annular-shaped multi-fiber guide may be either preformed separately and drawn to a desired cross-sectional size, or constructed at its desired size with appropriately sized fibers. Also, the multi-fiber annular guide may be separately used for applications other than the endoscope. Two techniques are disclosed for creating an opening in the sidewall of the annular illuminating guide through which the imaging bundle may exit at the proximal end of the endoscope. With one of the techniques disclosed herein, an enlarged opening is created between adjacent fibers without severing any fibers so as to minimize any disruption of the brightness and uniformity of the light at the tissue site.

In sum, using the techniques and structure disclosed herein, for the first time a low cost, disposable endoscope can be constructed utilizing closely packed, individually clad, plastic optical multi-fibers which are sufficiently efficient for this application in order to transmit both incident and returning light in a minimal cross-sectional area for successful viewing of tissue samples. While the principal advantages and features of the present invention have been discussed above, a greater understanding of the invention and its various embodiments may be attained by referring to the drawings and description of the preferred embodiment which follow.

Brief Description of the Drawings

Figure 1 is a partial, cross-sectional view of an endoscope utilizing the plastic, multi-fiber optic bundle assembly of the present invention;

5        Figure 2 is a partial, cross-sectional view taken along the plane of line 2-2 in Figure 1, detailing the catheter with the plastic, multi-fiber optic bundle assembly contained therein;

10       Figure 3 is a partial, cross-sectional view taken along the plane of line 3-3 in Figure 1, and detailing the separate fibers which comprise the plastic, multi-fiber optic bundle assembly;

15       Figure 4 is perspective view, detailing the separation point of the plastic, multi-fiber optic imaging bundle from the illumination fiber and the illumination fiber termination;

20       Figure 5 is a partial exploded view of the cladded, plastic, multi-fiber optic imaging bundle contained within the cladded illumination fiber, both being of substantially square configuration;

      Figure 6 is an alternative embodiment for the plastic, multi-fiber optic imaging bundle assembly wherein both the imaging bundle and the illumination fiber are circular;

25       Figure 7 is a partial, cross-sectional view of an alternative embodiment utilizing a square-shaped, plastic, multi-fiber optic imaging bundle with four illumination fibers positioned between the flat of each bundle side and the circular opening in the catheter;

30       Figure 8 is a cross-sectional view of an alternative embodiment for the plastic, multi-fiber optic imaging bundle assembly, wherein the imaging bundle is of square cross-section and the illumination fiber is of circular cross-section;

35       Figure 9 is a side view of an alternative embodiment of the plastic, fiber optic imaging bundle as-

sembly wherein both the imaging bundle and the illumination fiber are tapered;

5       Figure 10 is a partial, cross-sectional view of an alternative lens mounting arrangement at the end of the plastic, multi-fiber optic bundle assembly;

      Figure 11 is a schematic representation, showing the arrangement of the optics for utilizing a portion of the multi-fiber optic imaging bundle for illumination;

10       Figure 12 is a schematic representation of the optics for utilizing a beam splitter wherein the entire multi-fiber optic bundle assembly is used for both illumination and imaging;

      Figure 13 is a frontal view of a mechanism for drawing fibers;

15       Figure 14 is a series of views of a vacuum fixture in exploded "story board" format, illustrating its assembly for use in preparing clad billets of preform material for forming tapered fibers;

20       Figure 15 is a frontal view of an apparatus useful for forming the clad billets of material which incorporates the vacuum fixture of Figure 14;

      Figure 16 is a side elevational view of a de-inhibiting column used to separate the inhibitor from styrene monomer;

25       Figure 17 is a side elevational view of a distiller used to distill styrene;

      Figure 18 is a side elevational view of an aluminum tube used for forming the raw preforms;

30       Figure 19 is a cross-sectional view of a raw preform wrapped in aluminum foil inside of an aluminum tube;

      Figure 20 is an elevational view of an oven with a plurality of aluminum forms placed therein for heating; and

35       Figure 21 is an elevational view of a raw preform after polymerization into a solid.

Figure 22 is a perspective view of the mandrel and tube filled with individually cladded plastic optical fibers for fusing into the annular illuminating guide;

5 Figure 23 is a partial view of an assembled imaging fiber surrounded by the multi-fiber annular illuminating guide;

Figure 24 is a partial view of an assembled imaging fiber surrounded by a multiple row, multi-fiber annular illuminating guide;

10 Figure 25 is a perspective view of the separation point between the imaging fiber and the multi-fiber annular illuminating guide;

15 Figure 26 is a partial cross-sectional view taken along the plane of line 26-26 in Figure 25 and detailing the separation point between the imaging fiber and the illuminating guide;

20 Figure 27 is a perspective view of the separation point between the imaging fiber and the multi-fiber annular illuminating guide wherein adjacent fibers are separated to form the separation point; and

Figure 28 is a cross-sectional view of the multi-fiber illuminating guide with a heated mandrel inserted therein to create the separation point as depicted in Figure 27.

25 Detailed Description of the Preferred Embodiment

An endoscope 20 is shown in Figure 1 which includes the plastic multi-fiber optic bundle assembly 22 extending through a first opening 24 of the catheter 26. The bundle assembly 22 includes a plastic multi-fiber optic imaging bundle 28 contained within a generally hollow optical fiber 30. As is explained in greater detail, infra, the multi-fiber bundle 28 is comprised of a plurality of cladded plastic fibers arranged in an array, each fiber being an array or even an array of arrays to thereby have approximately 6,000 separate cladded pixels in a square array approximately 0.5 mm wide,

30

35

with a clad-to-core ratio of approximately 50%. Similarly, the hollow optical fiber 30 is also a clad plastic optical fiber to provide improved brightness and uniformity of illuminating light.

5           Although various materials may be used for both the core and cladding, all as is well known in the art, they may be chosen generally from the following. For the core: polystyrene, polymethylmethacrylate (PMMA), polycarbonate, acrylic butylstyrene, polymethylpentene, polyacrylate, and copolymers of polystyrene and acrylonitrile. For the cladding: co-polymers of polystyrene and acrylonitrile, co-polymers of polystyrene and polymethylmethacrylate (PMMA), acrylic butylstyrene, polymethylpentene, and polycarbonate. The inventors have worked with  
10           atactic polystyrene for core and acrylic for cladding. However, it is believed that any of the above materials may be equally used as is well known in the art.  
15

          In order to produce fibers using the methodologies disclosed herein, it is important that the thermal properties for the core and clad material be matched as they  
20           are heated and drawn after being assembled (as explained below) into a preform. These thermal properties include shrinkage ratios as the fiber cools after drawing, flow temperature, melt flow rate, the distortion temperature under load, and the water absorption in weight gain after  
25           24 hour immersion. All of these parameters are well known for the materials mentioned herein.

          The size of the fibers, and their packing densities in the multi-fiber constructed imaging fiber is  
30           determined by choosing a desired clad-to-core ratio. By that is meant the ratio of the total thickness of clad to that of the core, as measured along an edge of a fiber as found in the cross-sectional face or surface of the imaging fiber bundle. Generally, ratios between about 10% -  
35           60% are acceptable. Fibers with ratios approaching 60% however become marginal in their ability to transmit

light because of the reduced size of each core. In fibers approaching a 10% clad-to-core ratio, a greater amount of light is transmitted because of the greater size of each core. Fibers having just over one micron cladding thickness have been made and appear to approach a minimal dimension which must be maintained in order to ensure reliable optical performance of each fiber contained within the multi-fiber array. In other words, fibers having cladding less than one micron may be found to be not reliably efficient in transmitting light along an appreciable length. Therefore, for fibers ten microns on a side, two microns may be clad while the remaining eight microns may be core. This particular fiber construction yields a 25% clad-to-core ratio (two microns clad divided by eight microns core) which as stated above is within the range of acceptable ratios for a multi-fiber construction.

Still another parameter which measures the performance of the individual fibers is the acceptance angle or numerical aperture. Ideally, the acceptance angle of a fiber should approach  $90^\circ$ , correlating to a numerical aperture of one, which means that rays of light which impinge on any point in the fiber at any incident angle will be accepted into the fiber and transmitted thereby. Thus, all of the light impinging upon a cross-sectional face of the fiber will be accepted thereby independently of the light's incident angle. The numerical aperture may be mathematically derived from the indices of refraction for the core and clad. For good optical performance, the core material is different from the clad material in their refractive index. Also, generally the core refractive index is greater than the clad refractive index. For the preferred embodiment mentioned above with polystyrene core material and acrylic cladding, the indices of refraction are 1.5884 (core) and 1.49 (clad) yielding a numerical aperture of .55. This means that

not all of the light impinging on the face of the core is transmitted thereby. However, fibers having this composition have been found to function satisfactorily. A fiber constructed of different materials with different refractive indices would yield a different numerical aperture.

As shown in Figure 1, the plastic multi-fiber optic imaging bundle 28 exits from the optical fiber 30 at a separation point 32 which is mechanically reinforced by sleeve 34. The optical fiber 30 is terminated in a bulb 36 and a light source 38 is arranged to illuminate bulb 36 for transmission of illuminating light along the length of optical fiber 30. One or more optical elements 40 interface between the end of imaging bundle 28 for focusing the image at the proximal end 42 of endoscope 20. At the distal end 44, another optical element 46 is mounted at the end of the bundle assembly 22 and serves two purposes. The first of these is to scatter the illuminating light emanating from the optical fiber 30 across the field of view and the second purpose is to focus the returning light back into the imaging bundle 28. Optical element 46 may be a graded index of refraction lens for collimating the light to enhance the transmissibility thereof through the imaging bundle 28. A working channel 48 may be formed in the catheter 26 and used to collect tissue samples, flush the tissue with saline for clearer viewing or for other purposes as is well known in the art.

As shown in Figure 2, the bundle assembly 22 is sized such that its cross-sectional area is substantially the same as that of the first opening 24 extending through the catheter 26. Thus, maximum use is made of the space in first opening 24 which minimizes the cross-sectional area of the catheter 26.

This helps improve the flexibility of the catheter while contributing to a smaller endoscope 20. Further-



more, as shown in Figure 2, the first preferred embodiment of the bundle assembly 22 is that of a square imaging bundle 28 contained within a square, single illuminating optical fiber 30. This imaging bundle 28 and fiber 30 are typically separately formed using the methods and techniques disclosed generally in the patent cross-referenced above and more particularly herein, and then inserted one within the other. If desired, the imaging and illuminating fibers may be fused.

The separation point 32 is more specifically detailed in Figures 3 and 4. As shown therein, a notchlike opening 50 is formed along the lower portion of optical fiber 30 through which the imaging bundle 28 exits. A first sleeve 34 surrounds the separation point 32 through notch 50 to provide mechanical support to both fibers thereat. Additionally, a second sleeve 52 may surround the imaging bundle 28, first sleeve 34, and optical fiber 30 to help fix the bundle 28 and fiber 30 in position and prevent damage thereto during use of the endoscope 20.

As shown in Figure 5, cladding 54 surrounds optical fiber 30. Additionally, cladding 56 surrounds each of the individual fiber members 58 forming the imaging bundle 28. For those fiber members 58 which are comprised of multi-fiber bundles, each of their respective members (not shown) are also surrounded with cladding. All of this structure is understood to be included within the various embodiments disclosed herein. Furthermore, this teaching is generally disclosed and explained in the patent cross-referenced above and more specifically herein for fibers having smaller cross-sectional areas. The use of cladding substantially improves the light transmissibility of the individual fibers.

Alternative embodiments to the "square within square" construction for the bundle assembly 22 are shown in Figures 6-9. Any of these may be constructed and used in place of the "square within square" embodiment shown

as the preferred embodiment in Figures 1-4. As shown in Figure 6, a circular multi-fiber imaging bundle 60 may be inserted through the center of a generally circular or annular optical fiber 62 for illumination. In this embodiment, the first opening 24 would be generally circular to match the cross-sectional area of the bundle assembly 64 shown in Figure 6. Still another variation of the same approach is shown in Figure 8 and includes a bundle assembly 66 having a generally square multi-fiber imaging bundle 68 contained within a generally circular optical illuminating fiber 70 having a generally square opening therein. As with the embodiment of Figure 6, the first opening 24 through the length of the catheter 26 would be generally circular to match the cross-sectional area of the bundle assembly 66 shown in Figure 8. Still another variation is shown in Figure 9 which includes any of the constructions disclosed in Figures 1-4, Figure 6, or Figure 8, except that a taper is added along the length of both the imaging bundle 72 and the optical fiber 74 through which it is inserted. In other words, the bundle assembly 76 shown in Figure 9 may have the geometry of either a "square within square", a "circle within circle", or a "square within circle".

In a slightly different approach, the embodiment as shown in Figure 7 utilizes a multi-fiber imaging bundle 78 with a generally square, cross-sectional area to match a generally circular, first opening 24.

The cross-sectional shape of imaging bundle 78 is chosen such that the dimension across its diagonal is substantially that of the diameter of first opening 24. This creates openings between each flat side of imaging bundle 78 and the inner wall of first circular opening 24. Within each of these spaces, a single optical fiber 80 may be inserted to provide multiple paths for transmitting the illuminating light along the length of catheter 26. The diameter of each optical fiber 80 is chosen

such that it fits snugly in its associated space and is thereby held in position by the difference in shape between the multi-fiber imaging bundle 78 and first opening 24. This eliminates the need for extra layers or collars or the like to maintain their relative positions along the length of the catheter 26. This embodiment has the advantage of improved flexibility in that the "solid" illuminating fiber which surrounds the imaging fiber in the other embodiments is eliminated, and four smaller, more flexible fibers are used instead. Furthermore, these four fibers provide a more even distribution of light yielding more uniform illumination of the tissue.

As an alternative embodiment for the mounting of lens 46 within the distal end of first opening 24 and catheter 26, an arrangement is shown in Figure 10 whereby a lens 82 is inserted within the confines of optical fiber 30 and butted against the end of imaging bundle 28. In this configuration, incident light is projected from the ends of optical fiber 30 directly onto the tissue being examined and reflected light returns through lens 82 into the imaging bundle 28. In this configuration, incident light does not traverse lens 82 as it does lens 46 in the embodiment shown in Figure 1.

In still another alternative embodiment, a single plastic multi-fiber optic imaging bundle 84 may be used to transmit both incident and reflected light in one of the two arrangements as shown in Figures 11 and 12. Taking Figure 11 first, a mirror 86 may be aligned with an incident light source 88 to project incident light into a pre-selected portion comprised of a pre-selected number of discrete fibers contained within a single, integrally formed, plastic multi-fiber bundle 84. This incident light is thus confined to those fibers throughout the length of the multi-fiber bundle 84. Returning light for viewing the image may then be collected from those fibers not blocked by mirror 86 and focused with

one or more optical elements 90 for viewing. In this configuration as shown in Figure 11, a single multi-fiber bundle 84 conducts both incident and reflected light for both illuminating and imaging the tissue specimen. In order to enhance the separation of illuminating light from returning light, extra cladding 87 is added between the first and second portions of the bundle.

Although the arrangement is shown schematically in Figure 11 as utilizing only the upper discrete fibers of multi-fiber bundle 84, it would be understood to one of ordinary skill in the art that any one or more portions of the multi-fiber bundle 84 could be used for illumination. For example, multiple mirrors 86 could be utilized to illuminate a ring around a central imaging area of the multi-fiber bundle 84 such that a similar functional result could be obtained as that achieved by the other embodiments disclosed herein. However, a single, integrally formed, plastic fiber optic bundle would be used for both light transmissions, thereby eliminating the steps required to separately form an illuminating fiber optic and assemble it to the imaging bundle.

As shown in Figure 12, another variation would be to utilize a beam splitter 92 in place of mirror 86 such that the entirety of the multi-fiber bundle 84 could be used for transmitting both incident as well as returning light. However, in this configuration, light intensity can be a problem with some applications because of the tendency for the beam splitter 92 to attenuate the returning light. Therefore, there are some practical limitations to this application which must be compensated for. One of those compensations involves using the multi-fiber bundles made in accordance with the method and teaching herein and of the parent referenced above.

Both the single cladded fibers and the individually cladded multi-fibers useful in this invention can be prepared from preforms in a novel manner using the ap-

paratus 300 shown in Figure 13. The present method and apparatus involve slowly feeding a preform into an oven while pulling on the other end of the preform with a motorized pinch wheel to tension the preform and control the size of the fiber. A micrometer constantly measures the size of the fiber thus formed and its readout is used by an operator to adjust the speed of the motorized pinch wheel to maintain desired fiber thickness.

A general overview of the fiber optic forming apparatus 300 is shown in Figure 13. As shown therein, a fiber optic substrate in the form of a preform 304 is positioned within an oven 311 by a cable 306 which is attached to the top of the preform 304 and which extends around a pulley 308 to a motorized lead screw 309. A heater band (not shown) located near the lower end of oven 311 controllably melts the preform 304 through approximately a two inch wide area. The melted preform 304 thus may be drawn into a fiber of reduced size 304a by the motorized pinch wheel assembly 305. A cooling band 307 cools the fiber 304a before it contacts the motorized pinch wheel assembly 305 to solidify it and prevent its unintended deformation. A micrometer 312 continuously monitors the thickness of fiber 304a as it is formed with finished fiber being wrapped continuously about a motorized take-up wheel 314. By controlling the temperature of the oven, the speed of which the preform 304 is fed into the oven and the speed at which the motorized pinch wheel 305 pulls the fiber from the softened area of the preform 304, the size of the fiber 304a is controlled to achieve the desired fiber optic size.

The preform can be a two component structure comprising a center core and an exterior cladding. In a preferred embodiment, it can be a multi-fiber preform made up of a plurality of prefibers bonded together. In the multi-fiber preform, the cross-section of each of the

fibers is preferably square. These pre-fibers are formed into a solid preform rod referred to herein as a multi-boule and which may be used with this process to form multi-fibers.

5           As noted previously, in preferred embodiments of this invention, each of the individual fibers used herein is clad-  
10           That is, each fiber comprises a core formed from a light-transmissive material, which core is surrounded by a cladding formed from a material having a refractive index different from the core material. Figure 14 illustrates one way to form these materials from clad preforms or billets. This invention additionally provides a new method and device for forming these clad-  
15           ded preforms or billets.

15           Turning to Figure 14, a block or load of optically transmissive plastic 330 is formed, as described below. This block has a defined shape, including a cross section 332 and length L. This will become the core inside the cladding material. It is fitted within a hollow sleeve  
20           of cladding material 334. The cross section 336 of the hollow opening of sleeve 334 corresponds to the cross section of core 330 so that the core may be slid inside. These dimensions should be closely tailored so that the space between the core and the cladding is relatively  
25           minimal. This cladding with its enclosed core is then fitted within the hollow aluminum fixture 338. The cross section 340 of this hollow is sized to receive the outside dimensions of sleeve 334. The length L of the core, the length L' of the sleeve, and the length L" of the  
30           aluminum fixture are all substantially identical. Fixture 338 may be somewhat longer than the other two components, if desired. Fixture 338 is formed of a solid material capable of good heat transfer and also capable of withstanding substantial positive pressure. Aluminum  
35           or other metals are preferred materials of construction. The aluminum fixture loaded with core 330 and cladding

334 is placed inside closable pressure box 342. Pressure box 342 has an interior cavity 344 having interior dimensions somewhat larger than the exterior dimensions of fixture 338 so that fixture 338 may fit inside. Pressure box 342 is equipped with an O-ring seal and a replaceable door 348, which is sealably bolted to the opening of the box, thereby forming an enclosed pressure-tight box. Pressure box 342 is equipped with pressure rams or plungers 352 and 354. These plungers appear at opposite ends of the fixture and have plunger heads sized to fit into the end cavities of fixture 338. Thus when these two pressure rams move inwardly on their shafts 356 and 358, respectively, they impinge upon and compress the body of cladding material 334 and core material 330 contained within fixture 338.

Turning now to Figure 15 the use of this cladding fixture in the cladding process of this invention is illustrated. In Figure 15 three pressure boxes 342, 342a, and 342b are illustrated mounted within oven 360. In use, a vacuum supplied by vacuum pump 362 is applied to the interior of each of the three boxes. The oven 360 is heated gradually from room temperature to about 125°C. This takes about one hour. After about two hours, the core and cladding materials contained within the boxes are heated to a point that they are becoming plastic and flowable. Pressure is then applied to the plungers via shafts 356, 358, 356a, 358a, 356b and 358b via drive units 364 and 366, 364a and 366a, and 364b and 366b, respectively. These drive units can be motorized or can be pneumatic or hydraulic. A pressure is raised to about 1600 psi and should be a slow, steady application of pressure. Preferably, the pressure is increased from about 1000 to 1600 psi over a 3-5 minute period. Pressure is held constant at this 1600 lb level for about one-half an hour. The rams may gradually move inward during this period as the two plastics flow and fill.

Then the heat is turned off, and the vacuum is turned off. The three vacuum boxes are allowed to cool to room temperature. No additional pressure is applied and as the system cools, the plastic in the vacuum boxes contracts, thereby automatically releasing the pressure. Thereafter, the vacuum boxes are opened, the plungers are retracted, and the fixtures such as 338 are withdrawn from the vacuum boxes. The plastic contained within the fixture 338 may then be removed from the fixture 338. The product so formed is a core surrounded by a concentric cladding wherein there is intimate contact between the clad and core without migration.

This sleeved product will typically be several inches in cross-section. It can be drawn to some smaller size either to form a single unit preform for tapering or, more preferably, drawn further to a pre-fiber size having a reduced cross-sectional area for forming into a multifiber preform.

The cladding conditions just described, are exemplary. Any dimensions which will give rise to a suitable ratio of cladding material to core material may be used. For best results, the cross-sectional area of the fiber should be at least four times the cross-sectional area of the cladding. Also, preferably, the minimum effective width of the cladding is about one micron. This dimension is believed to provide a practical limit to the minimum fiber size which can be drawn from these particular preforms. Similarly, any shape, for example circular, octagonal, pentagonal, square, rectangular, or any regular polygon may be used. Typical forming temperatures can range from about 100°C to about 300°C and may be higher, if the materials used will permit. So too the forming pressure may range from about 800 psi. to about 3000 psi, or preferably from about 1000 to about 2000 psi. Typical forming times may be from about 5



minutes to several hours. Longer times could be used, if desired.

Referring now to Figures 16-21, the distillation and polymerization process for forming raw preforms will be described. As shown in Figure 16, a quantity of commercial grade styrene monomer 200 is filtered by placing it first in a beaker 202 with a glass tube 204 for drawing the styrene 200 therefrom and into a second, larger glass tube 206 which has a reduced neck 206a at its lower end and which contains a plurality of de-inhibiting beads 208. The styrene is then permitted to flow through glass tube 206 and beads 208 which filter out the inhibitor normally present in commercial grade styrene monomer (as known in the art) such that the inhibitor has been removed from the styrene monomer 210 collected in a second glass beaker 212. Referring now to Figure 17, the beaker 212 containing the styrene monomer 210 may then be used to supply the filtered styrene monomer 210 into a rotary distiller, generally identified as item 214. The rotary distiller may be any rotary distilling device presently available such as a Rotavapor Model R-151. The styrene monomer 210 is fed into a rotating glass beaker 216 and heated to approximately 50°C under approximately 3 millibars of negative pressure at which point it vaporizes, leaving behind the contaminants, impurities, and any other substances other than the styrene monomer. The vapor then condenses on a condensing coil 218 which is refrigerated by refrigerator 220, as known in the art. The filtered, distilled styrene monomer 222 is collected in a collection beaker 224 and is then available for further processing. As shown in Figure 18, an aluminum tube 226 having a substantially square cross-section is used as a mold and, as shown in Figure 19, an envelope of aluminum sheet or foil 228 serves as a barrier between the filtered, distilled, styrene monomer 222 and the aluminum mold 226. The mold 226 filled with styrene

monomer 222 is placed in an oven 230 as shown in Figure 20 to accelerate the polymerization of the styrene monomer into a solid. This process is generally achieved at temperatures between 115°-125°C for 3-5 days. After polymerization has been achieved, a raw preform 232, as shown in Figure 21, is formed and is ready for further processing by machining into a nominal 1-3/4" square. After machining, cladding is applied to the raw preform 232 and fibers are drawn therefrom.

In addition to the methods and practices disclosed in the parent, the inventors herein have developed additional methods for assembling and fusing the individually cladded plastic fibers into arrays. Because the fibers being worked with for this application of an endoscope are much smaller than those used in the particular application disclosed in the parent, additional techniques are disclosed herein in order to ensure the accurate and convenient assembly of these fibers into coherent bundles. By using the apparatus and processes disclosed above, a first single cladded fiber may be drawn and wrapped around the wheel shown in Figure 13 in adjacent wraps of twenty or more. Each fiber may be as small as one millimeter or less in size. The wraps are abutting and consecutive which is easily achieved by feeding the fiber onto the wheel as the wheel rotates, the drawing process being of a speed to conveniently accommodate wrapping the fiber in this manner. After twenty or more wraps are attained, tape or the like is used to fix the adjacent fibers at a plurality of locations about the circumference of the wheel. Of course, glue or other fixative could be used as well. After being affixed, a cut is made through the tape to form ribbons of fibers, each ribbon being comprised of a single row of twenty or more fibers fixed in place at each end with a strip of tape. These ribbons may be further subdivided lengthwise in order to assemble a plurality of

rows having a desired number of individual fibers therein. For example, the inventors have found that ribbons having twenty fibers are convenient to work with. These ribbons are then stacked to create a matrix of fibers, the preferred matrix being  $n \times n$ ,  $n$  being an integer. Additionally, several of these matrices may be assembled into an  $m \times m$  boule,  $m$  being an integer, once again using tape or some similar fixative to hold the matrices in place. In this manner, boules can be conveniently formed comprised of fibers of reduced size which would otherwise be very difficult to handle by hand.

By forming ribbons comprised of a single row of twenty or more fibers, it is possible to maintain dimensional tolerances across a row of fibers that would otherwise be very difficult to do if imposed on individual fibers. Of course, dimensional tolerances between pixels is important in that a greater range in pixel size results in a greater amount of distortion in any image viewed through the multi-fiber. Individual fibers found to be out of tolerance can be easily removed or avoided by carefully selecting the fibers to be included in any lengthwise cut of a ribbon. Of course, if individual fibers are handled by hand, then individual fibers can be individually measured for tolerances and used or discarded, as appropriate.

After the individually clad fibers are assembled first into ribbons, then matrices, and then into a boule, and fixed with tape or other fixative, the boule may then be fused to join the fibers along the entirety of their length. This process is important as a fused boule may then be processed with the same procedures, as shown herein in order to create a single fiber of substantially reduced cross-sectional area. As previously explained, these individual multi-fibers may then also be processed in the same manner a second and even a third time to create a finished fiber having thousands of pixels while

measuring only one millimeter or less. However, using the "ribbon" process disclosed herein permits the formation of multi-fibers suitable for use in the endoscope with only two draws.

5           This fusing process is a two-step fusing process. The first fuse requires a vacuum oven which heats a boule wrapped in a polytetrafluoroethylene jacket and placed in a fixture, with temperatures and vacuum pressures maintained for the times as indicated in the following table.

	<u>Temp</u>	<u>Vacuum</u>
10           T = 0	25°C	.5-.75 mm mercury
	1 hr. 50-75°C	.6-.7 mm mercury
	2 hr. 75-125°C	.8-.9 mm mercury
	3 hr. 145°C	1 mm mercury
15           +1/2 hr. 145°C		1 mm mercury

Total Time = 3-1/2 hrs.

After the completion of the first fuse in approximately 3-1/2 hours, the boule is removed from its polytetrafluoroethylene jacket and rewrapped with .5 mil  
 20 polytetrafluoroethylene and then a 1 mil polyethylene terephthalate film. The boule is then placed back into an aluminum tube-type fixture where it is heated in an oven at atmospheric pressure for a period of five hours while the temperature is increased from 25°C to 150°C,  
 25 and then maintained at 150°C for an additional hour after which the oven is turned off. After this second fuse, the finished boule or rod is ready for drawing in this manner.

A further embodiment is shown in Figures 22-28 for  
 30 the annular illuminating fiber optic guide. As shown in Figures 22 and 23, a multi-fiber optic illuminating guide 100 is comprised of a plurality of individual fibers 102 each of which has its own cladding 104 surrounding a core 106. Individual fibers 102 may themselves either be  
 35 solid fibers or multi-fibers with a large number of pixels. Also, as shown in Figure 24, multiple rings 105 of fibers 102 could be used to form the annular illuminating

guide 100. Although square fibers 102 are shown fused in a generally annular shape, it is to be understood that other shapes of fibers could be used as well as other overall shapes for the multi-fiber optical guide 100.

5 For example, for square imaging fiber bundles, rectangular or "picture frame"

multi-fiber optical guides 100 may be used. This multi-fiber optical guide 100 surrounds the multi-fiber imaging bundle 108 and transmits incident light to the  
10 tissue site for illuminating the tissue under observation.

As shown in Figure 22, the multi-fiber optical illuminating guide 100 is constructed by assembling a plurality of individual fibers 102 (either discrete or  
15 multi-fiber) about a mandrel or rod 110 which has first been wrapped with polytetrafluoroethylene 111 having a 1.5 mil thickness, the wrap either being a spiral wrap with overlapping edges or a longitudinal wrap also having an overlapping edge. A sleeve 112 surrounds the fibers  
20 102 and is used to hold them temporarily in place until a layer of tape 114 or the like secures the fibers around the mandrel 110, and at both ends thereof. Once the fibers 102 are secured, they are wrapped with another layer of 1.5 mil polyethylene terephthalate 115. Sleeve  
25 112 is then replaced to completely surround the wrapped and taped fibers 102 and mandrel 110.

Once the fiber optic mandrel assembly has been prepared, it is placed in a vacuum oven and fused and heated for the time periods as indicated in the following  
30 table.

	<u>Time</u>	<u>Temp</u>	<u>Pressure</u>
	1/2 hr.	50°C	5 mm. Hg
	1/2 hr.	65°C	
	3/4 hr.	85°C	
35	1/2 hr.	100°C	
	3/4 hr.	125°C	
		50°C (cool down)	

After this first fusing, the fiber optic mandrel assemble is fused a second time at 50°C for .5 hour, 163°C for .75 hour, and then cooled to 50°C in the oven, after which it may be removed. The multifiber optic  
5   boule assembly may then be disassembled, polytetrafluoro-ethylene and polyethylene terephthalate wrappings re-  
removed, and the annular fiber optic illuminating guide 100  
10   is then ready for drawing using the same procedures as described above. Drawing of the multi-fiber optic illu-  
minating guide 100 permits it to be formed in any larger  
dimension and then drawn to the desired dimension to  
match the imaging fiber which extends through the central  
opening therein. Drawing also permits the formation of  
15   illuminating guides having multiple rings by inserting  
one guide of smaller size into a guide of larger size.  
These techniques permit manufacture of both illuminating  
fiber guides and imaging fibers to various configurations  
and dimensions in order to satisfy particular applica-  
tions.

20       As shown in Figures 25 and 26, the multi-fiber  
optic illuminating guide 100 has a separation point 120  
whereat the multi-fiber imaging bundle 122 exits from  
within the central opening thereof. At that juncture, in  
one embodiment, the individual fibers may be cut through  
25   to create the separation point 120 and an epoxy resin 124  
with an index of refraction matching that of the individ-  
ual fibers 102 may be used to join the surfaces of the  
cut fibers 102 so as to transmit light between the cut  
ends of the fibers 102. A non-transparent epoxy can be  
30   used to fill the interior and isolate the two bundles  
100, 122. Otherwise, discontinuities in the illuminating  
light seen at the tissue site might appear. This is best  
shown in Figures 25 and 26.

35       An alternative to cutting the individual fibers  
102 is shown in Figures 27 and 28. In that embodiment, a  
heated mandrel 130 is inserted radially between adjacent

fibers 132, 134 in order to create an opening therebetween of sufficient size for a separation point 136 through which the multi-fiber imaging bundle 138 may exit. As can be appreciated, while the individual fibers 132, 134 and additional surrounding fibers may be distorted, a substantial portion if not all of the light traversing the fiber continues therethrough so as to dramatically reduce any deleterious effects on the brightness and/or illumination of tissue at the distal end of the multi-fiber illuminating guide 100.

Various changes and modifications to the various embodiments of the invention disclosed above would be apparent to one of ordinary skill in the art. Accordingly, those changes and modifications are considered as falling within the teachings of the invention and the invention should be limited only by the scope of the claims appended hereto.

What Is Claimed Is:

1.

In an endoscope for viewing tissue inside a patient's body, the improvement comprising a cladded plastic optical guide for transmitting incident light to illuminate the tissue being viewed, and a plastic multi-fiber coherent imaging bundle for transmitting the image of the tissue being viewed, said imaging bundle comprising a plurality of cladded plastic optical fibers, and said illuminating guide surrounding a substantial portion of the periphery of the imaging bundle and extending over a substantial portion of its length.

2.

The endoscope of Claim 1 wherein the illuminating guide surrounds the entire periphery of the imaging bundle throughout said substantial portion of its length.

3.

The endoscope of Claim 2 further comprising a separation point at which the imaging bundle exits from within the illuminating guide, said separation point being near the proximal end of the endoscope, and further comprising means for reinforcing said separation point.

4.

The endoscope of Claim 3 wherein said illuminating guide is a single optical fiber.

5.

The endoscope of Claim 4 wherein a proximal end of said illuminating fiber terminates in a bulb, said bulb being adapted for maximizing the channeling of incident light through the guide itself.

6.

The endoscope of Claim 2 wherein said illuminating guide is comprised of a plurality of cladded plastic optical fibers.



31

7.

The endoscope of Claim 1 wherein said endo- scope includes a catheter, said catheter including a first opening through which both the imaging bundle and the illuminating guide extend, said imaging bundle and illuminating guide filling substantially the entire cross-sectional area of said first opening to thereby minimize the cross-sectional area of said catheter.

8.

The endoscope of Claim 7 wherein the illuminating guide surrounds the entire periphery of the imaging bundle throughout said substantial portion of its length.

9.

The endoscope of Claim 8 wherein said imaging bundle is substantially square in cross-sectional shape and said illuminating guide is substantially square with a square opening therein.

10.

The endoscope of Claim 8 wherein said imaging bundle is substantially square in cross-sectional shape and said illuminating guide is substantially round with a square opening therein.

11.

The endoscope of Claim 8 wherein said imaging bundle is substantially round in cross-sectional shape and said illuminating guide is substantially round with a round opening therein.

12.

The endoscope of Claim 1 wherein each of the fibers comprising the imaging bundle is itself comprised of a plurality of individually cladded plastic fibers.

13.

The endoscope of Claim 1 wherein the fibers forming the imaging bundle are arranged in an array, said

array having substantially no interstices between the  
outer clad surfaces of the fibers to thereby maximize the  
5 density of said fibers within the imaging bundle.

14.

The endoscope of Claim 13 wherein each of said  
imaging bundle fibers has the cross-sectional shape of a  
regular polygon.

15.

The endoscope of Claim 14 wherein the contour of  
the inner surface of said illuminating guide matches the  
contour of the outer surface or surfaces of said imaging  
bundle to thereby maximize the effective use of space  
5 within said endoscope.

16.

The endoscope of Claim 15 wherein the clad-  
to-core ratio of fibers within said imaging bundle is  
between about 10% - 60%.

17.

The endoscope of Claim 16 wherein the cladding for  
each of said imaging bundle fibers is polymethylmethacry-  
late and the core for each of said imaging bundle fibers  
is polystyrene.

18.

The endoscope of Claim 17 wherein the imaging  
bundle is substantially square in cross-section, is about  
0.5 mm long on each side, and contains approximately  
6,000 fibers, each of said fibers having a clad approxi-  
mately 1 micron thick and a core approximately 4.3 mi-  
5 crons wide.

19.

In a scope comprising a generally elongated  
body member, said body member having a first opening  
extending from at least near the scope's proximal end to  
at least near the scope's distal end, the improvement  
5 comprising a plastic fiber optic bundle assembly extend-  
ing through said first opening and having substantially

33

the same cross-sectional shape as that of the body member to thereby minimize the size of the body member, said bundle assembly being comprised of an imaging bundle having a plurality of individually clad plastic fiber members, and a cladded plastic optical fiber for transmitting incident light for illumination.

20.

The scope of Claim 19 wherein each of said imaging bundle members is itself comprised of a plurality of individually cladded plastic fibers.

21.

The scope of Claim 19 wherein the illuminating light optical fiber is a single cladded fiber which substantially surrounds said plastic multi-fiber imaging bundle.

22.

The scope of Claim 21 further comprising a separation point at which the imaging bundle exits from within the illuminating fiber, said separation point being near the proximal end of the scope, and further comprising means for reinforcing said separation point.

23.

The scope of Claim 21 wherein each of said imaging bundle and said illuminating fiber are tapered.

24.

The scope of Claim 19 wherein said scope is an endoscope adapted for viewing tissue within a human body.

25.

In a scope comprising a catheter, said catheter having a first opening extending from at least near its proximal end to at least near its distal end, said first opening having a substantially circular cross-sectional shape, the improvement comprising a plastic, multi-fiber imaging bundle having a substantially square, cross-sectional shape extending through said first opening, and a plurality of plastic illuminating optical fibers exten-

ding through said first opening, each of said illuminating fibers having a substantially circular cross-sectional shape and being positioned between one of the flat sides of said imaging bundle and the sidewall of said first opening.

26.

The scope of Claim 25 wherein said plurality of illuminating fibers comprises four, each of said illuminating fibers being positioned between each flat side of said imaging bundle and the sidewall of said first opening.

27.

A scope having a plastic multi-fiber optical bundle extending substantially the length thereof, said bundle being comprised of an integrally formed array of clad plastic fibers and means for utilizing said plastic, multi-fiber optical bundle for transmitting both incident light for illuminating a specimen and returning light for imaging the specimen.

28.

The scope of Claim 27 wherein said bundle utilizing means comprises means for focusing the incident light into only a first portion of said bundle, and means for focusing the returning light into a second portion of said bundle.

29.

The scope of Claim 28 wherein said incident light focusing means comprises means for focusing the incident light into a first pre-determined plurality of fibers, and said returning light focusing means comprises means for focusing the returning light into a second pre-determined plurality of fibers, said first plurality of fibers being different fibers from said second plurality of fibers.

35

30.

The scope of Claim 28 wherein said bundle utilizing means further comprises a mirror, said mirror being oriented to reflect light from a light source into said first bundle portion.

31.

The scope of claim 27 wherein said bundle utilizing means comprises a beam splitter, said beam splitter being oriented to reflect light from a source into substantially the entirety of said bundle.

32.

The scope of Claim 27 wherein said scope is an endoscope adapted for viewing tissue within a human body.

33.

5 An endoscope for viewing a specimen inside a patient's body, said endoscope comprising an illuminating fiber guide substantially surrounding an imaging bundle, said illuminating fiber guide being comprised of a plurality of cladded plastic fibers joined along their length to form a tube-like sleeve with a central opening for transmitting incident light to illuminate the specimen, and said imaging bundle comprising an integrally formed array of cladded plastic fibers for transmitting  
10 light returning from the specimen for producing an image thereof.

34.

The endoscope of Claim 33 further comprising a separation point located at a proximal end of said endoscope, said imaging bundle exiting from within said illuminating fiber guide at said separation point, said separation point comprising an enlarged opening between adjacent fibers in said guide so as to minimize any interruption in the illuminating light.

35.

The endoscope of Claim 33 wherein the fibers of said guide are fused to each other.

36

36.

5 The endoscope of Claim 33 further comprising a separation point located at a proximal end of said endoscope, said imaging bundle exiting from within said illuminating fiber guide at said separation point, said separation point comprising a hole cut through a plurality of said guide fibers, and means forming a replacement light path between the ends of said cut fibers to thereby minimize any interruption in the illuminating light.

37.

The endoscope of Claim 36 wherein said replacement light path forming means comprises an index of refraction matching epoxy resin.

38.

The endoscope of Claim 33 wherein both of said illuminating fiber guide and the imaging bundle each substantially has the cross-sectional shape of a regular polygon.

39.

The endoscope of Claim 33 wherein said illuminating fiber guide has the cross-sectional shape of substantially an annulus.

40.

The endoscope of Claim 33 wherein the cladde plastic fibers comprising each of the illuminating fiber guide and the imaging bundle substantially have the cross-sectional shape of a regular polygon.

41.

The endoscope of Claim 33 wherein the cladde plastic fibers forming the illuminating fiber guide are each comprised of an integrally formed array of cladde plastic fibers.

42.

The endoscope of Claim 33 wherein the illuminating fiber guide is comprised of a single ring of cladde plastic fibers.

37

43.

The endoscope of Claim 33 wherein the illuminating fiber guide is comprised of a plurality of rings of clad-ded plastic fibers.

44.

The endoscope of Claim 33 further comprising means for creating a gradient illuminating light emanating from said illuminating fiber guide.

45.

The endoscope of Claim 44 wherein said gradient illuminating light means comprises an illuminating guide comprised of a plurality of rings of cladded plastic fibers.

46.

The endoscope of Claim 45 wherein at least one of said rings is comprised of scintillating fibers.

47.

The endoscope of Claim 45 wherein said gradient illuminating light means further comprises a gradient light source.

48.

A method for assembling a plurality of plastic fibers of reduced size into an array of  $n \times m$  fibers comprising the steps of:

drawing a continuous plastic fiber;

5 wrapping said continuous plastic fiber about a wheel or the like into a plurality of non-overlapping, adjacent turns;

fixing together at least a plurality (n) of said adjacent turns at their ends;

10 cutting said fixed turns into a plurality of  $n \times 1$  groups;

stacking a plurality (m) of said groups to thereby form an array of  $n \times m$  fibers; and

38

15 fusing said groups of fibers so that they are  
joined along their length into a single multi-fiber array.

49.

The method of Claim 48 further comprising the step of assembling a plurality of  $n \times m$  arrays into a larger array, such as  $2m \times 2n$ , prior to fusing.

50.

5 The method of Claim 48 wherein the step of fixing includes the step of fixing together at least a plurality (n) of adjacent turns at a plurality of locations about said wheel or the like, and wherein the step of cutting includes the step of cutting said fixed turns at each of said locations.

51.

The method of Claim 48 further comprising the steps of inspecting said turns and eliminating those turns deemed undesirable prior to the step of fixing.

52.

5 A hollow plastic fiber optic guide, said guide being comprised of a plurality of individually clad plastic optical fibers, said fibers being joined along their length to substantially surround an interior space defined thereby.

53.

The guide of Claim 52 wherein said fibers surround the entirety of said interior space.

54.

The guide of Claim 52 wherein said fibers are joined by being fused to each other.

55.

The guide of Claim 52 wherein each of said fibers is itself an integrally formed array of clad plastic fibers.



39

56.

The guide of Claim 52 wherein said plurality of fibers are arranged in a plurality of generally concentric rings.

57.

The guide of Claim 52 wherein said fibers are arranged substantially in the shape of an annulus.

58.

A method for forming a hollow plastic fiber optic guide comprised of a plurality of individually clad plastic optical fibers, said method comprising the steps of:

5 stacking a plurality of said fibers in a confined space defined by a mandrel and sleeve;

fusing said fibers into said guide as they are positioned in said confined space; and

removing said guide from said confined space.

59.

The method of Claim 58 wherein the step of fusing includes the step of heating the fibers.

60.

The method of Claim 58 wherein the step of fusing includes the steps of:

5 interfacing the fibers from the mandrel and sleeve with wrappings of polytetrafluoroethylene and polyethylene terephthalate;

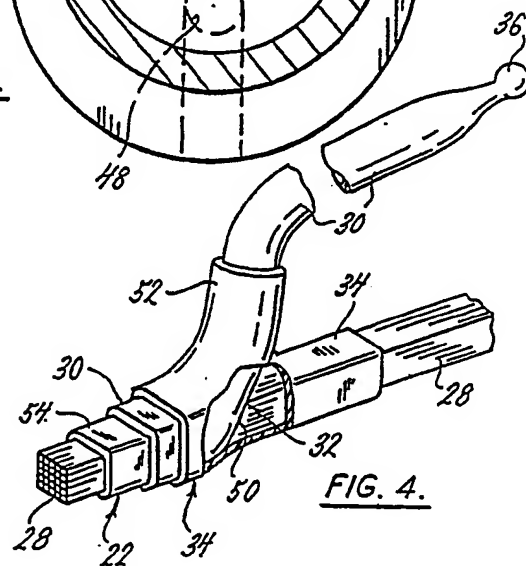
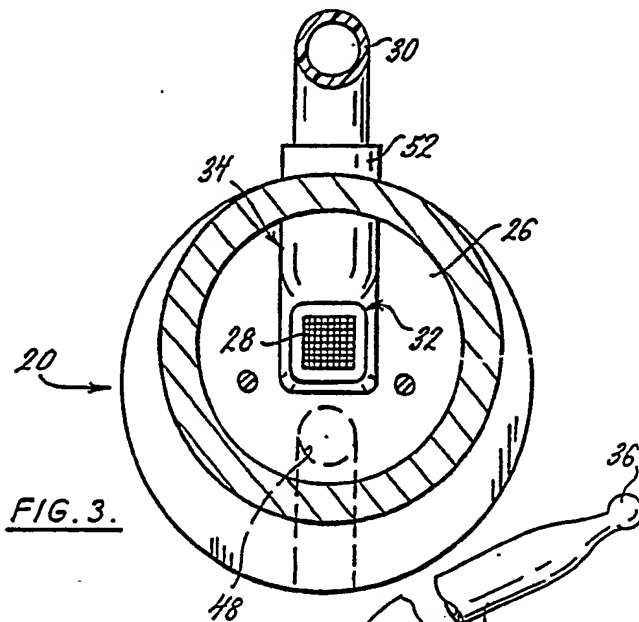
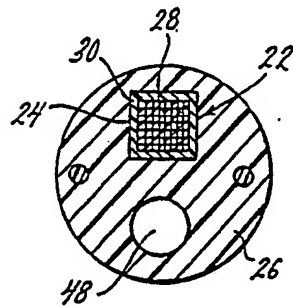
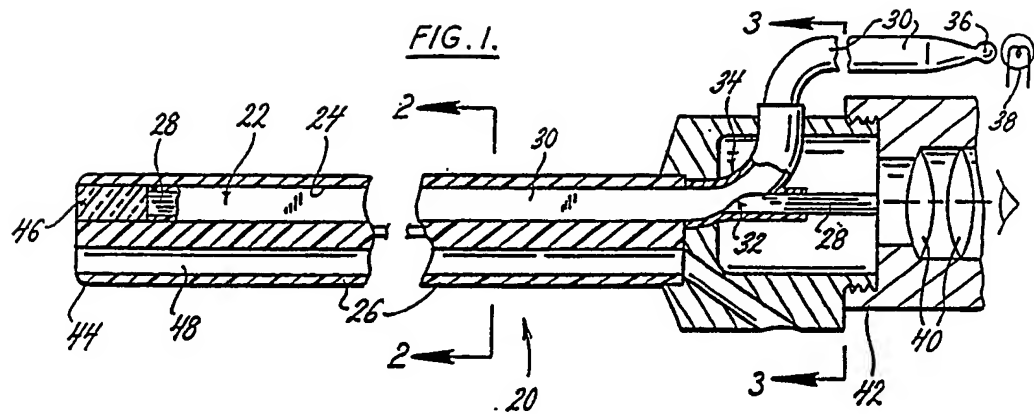
heating the fibers a first time under partial vacuum;

heating the fibers a second time at atmospheric pressure; and

10 removing the wrappings.

61.

An endoscope for viewing a specimen inside a patient's body, said endoscope comprising an illuminating fiber and an imaging fiber, wherein the illuminating fiber contains a scintillator dye.



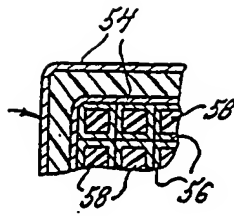


FIG. 5.

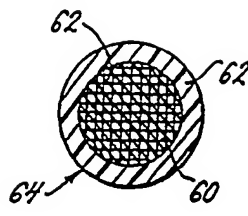


FIG. 6.

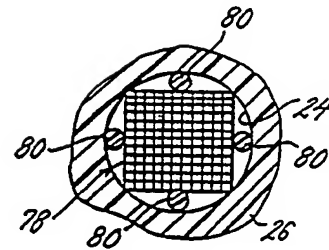


FIG. 7.

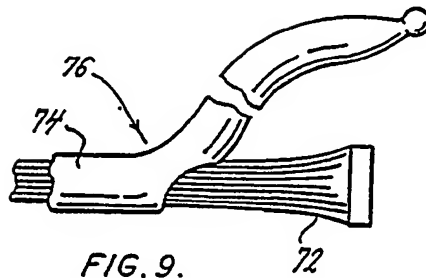


FIG. 9.

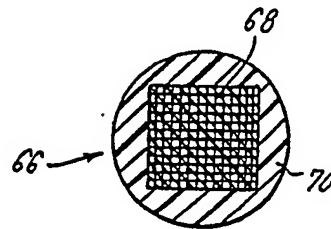


FIG. 8.

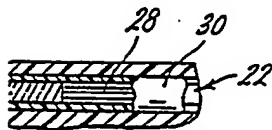


FIG. 10.

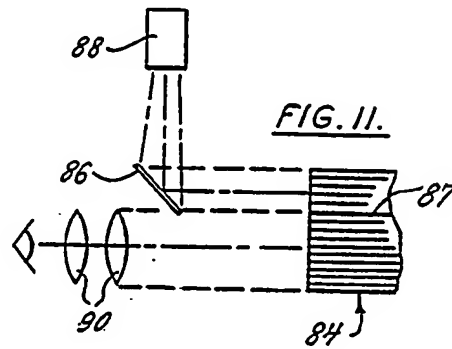


FIG. 11.

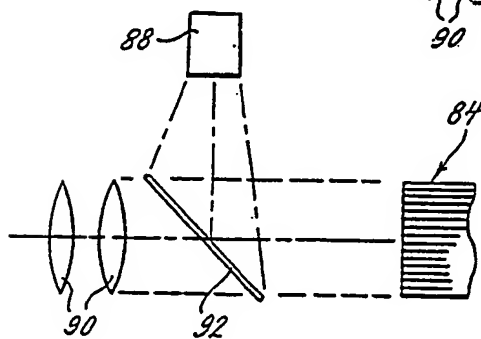
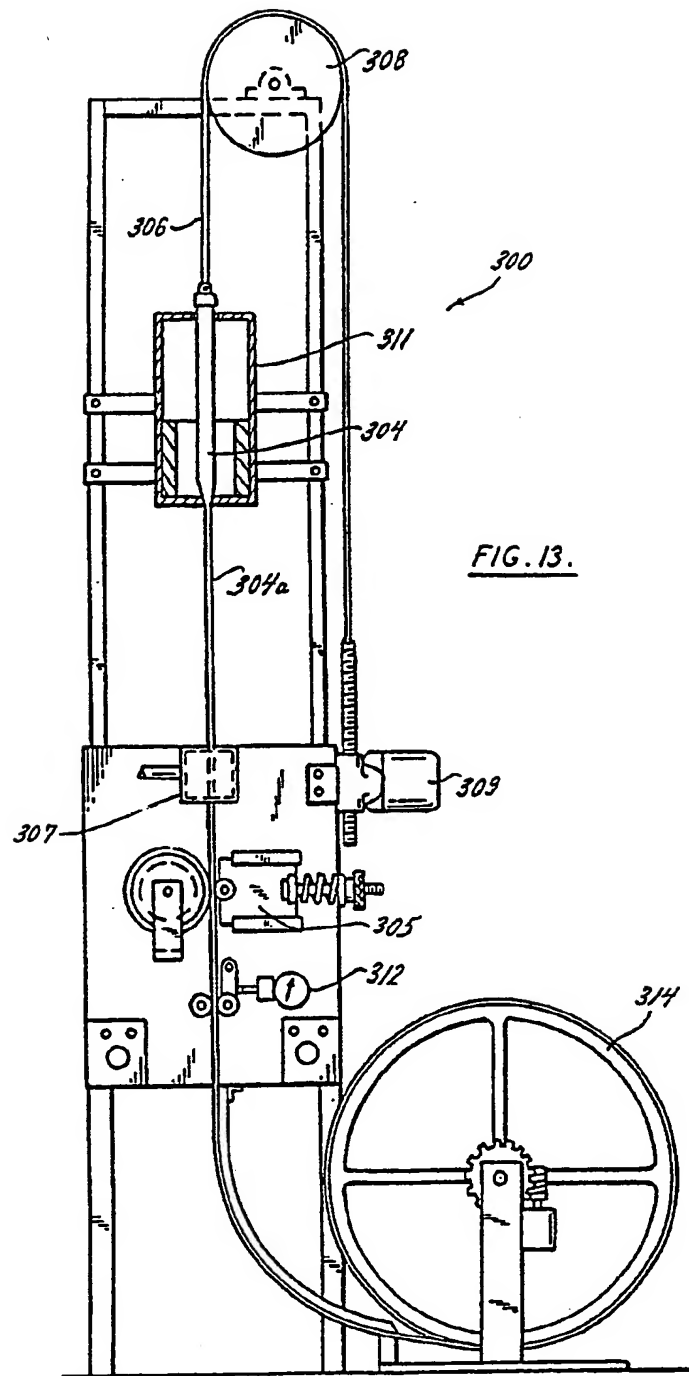


FIG. 12.



**SUBSTITUTE SHEET**

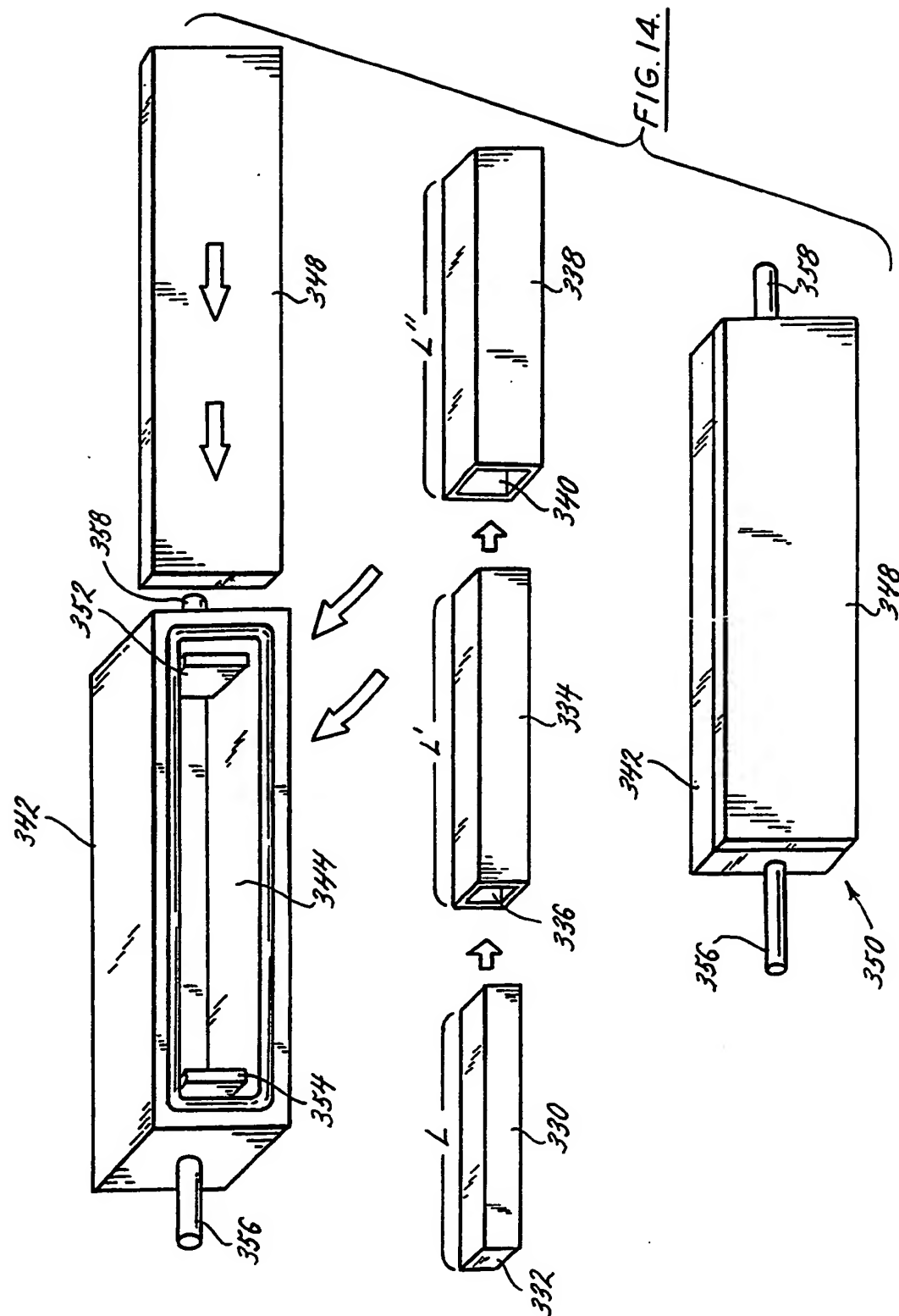
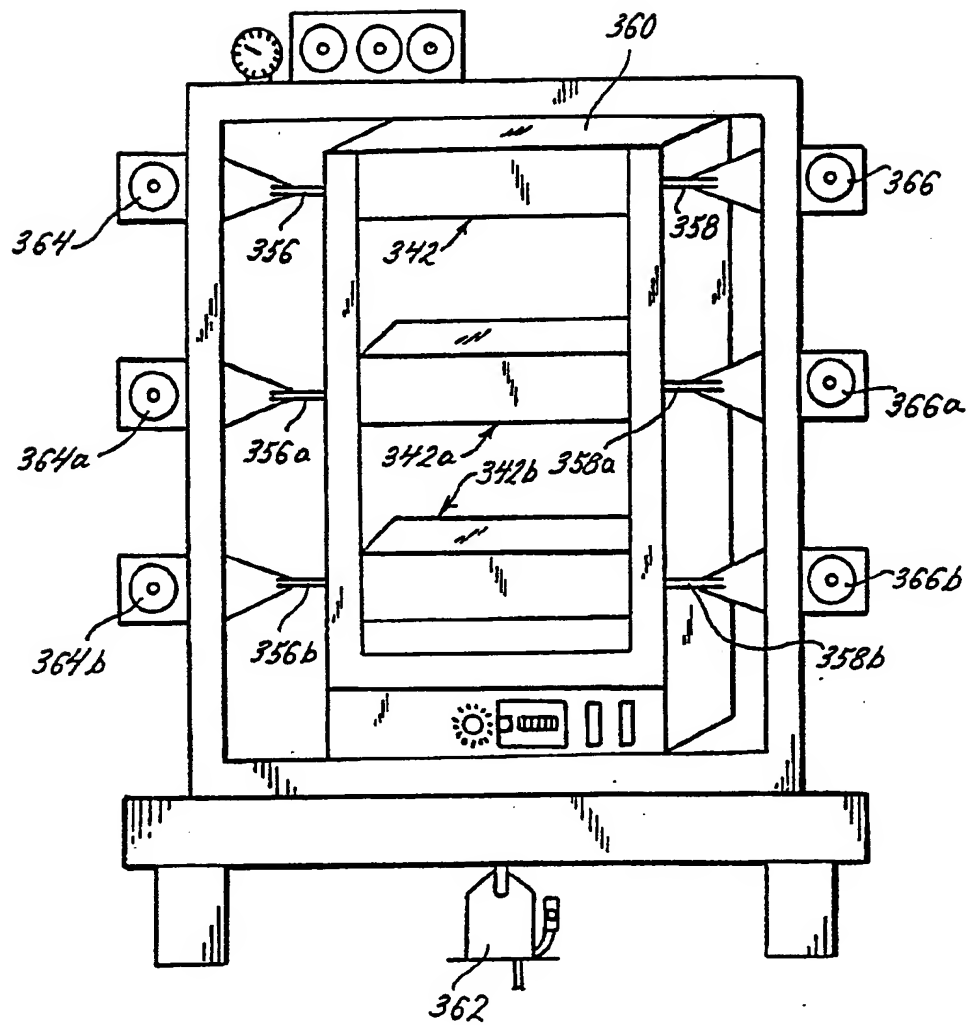
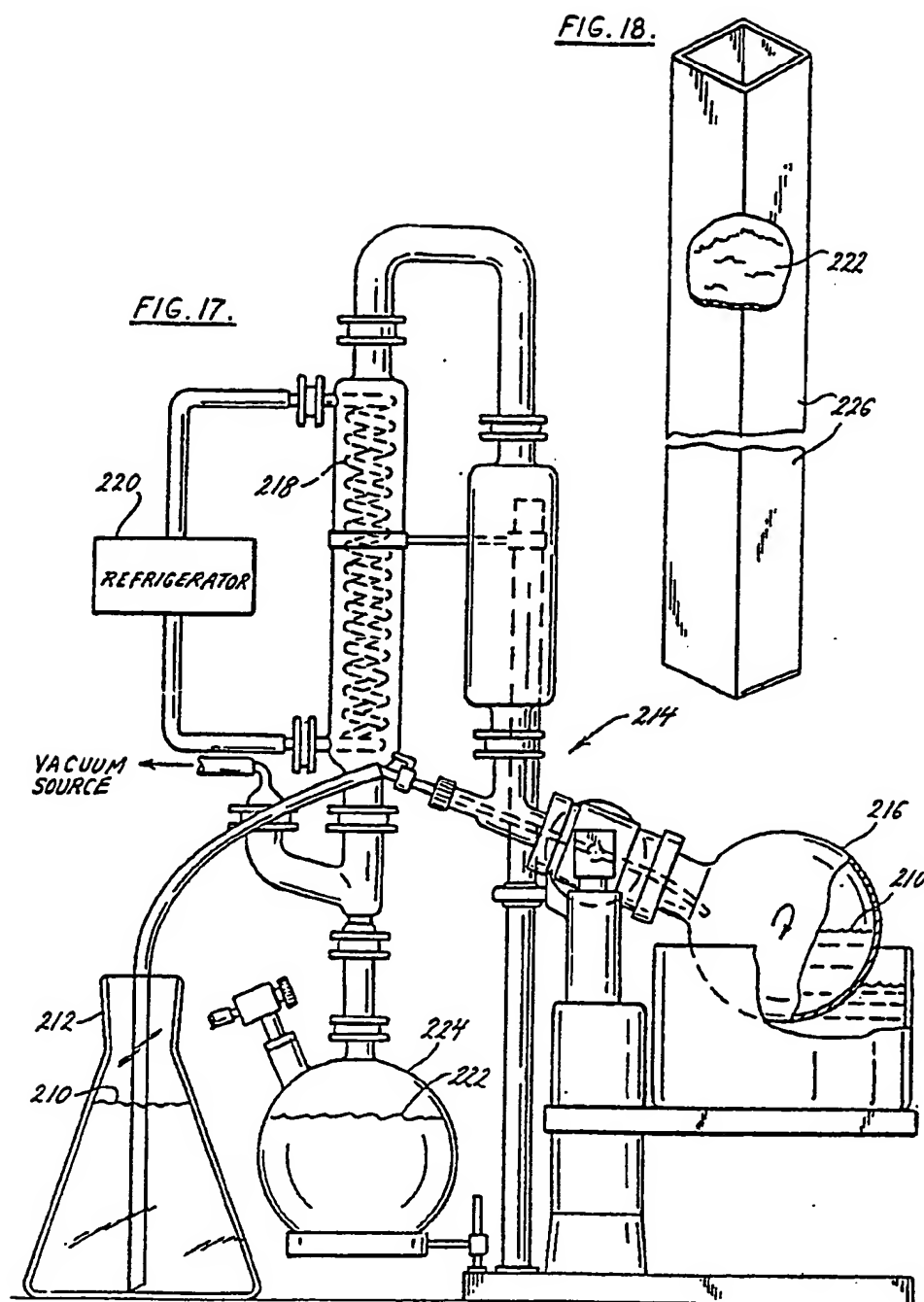


FIG. 15.



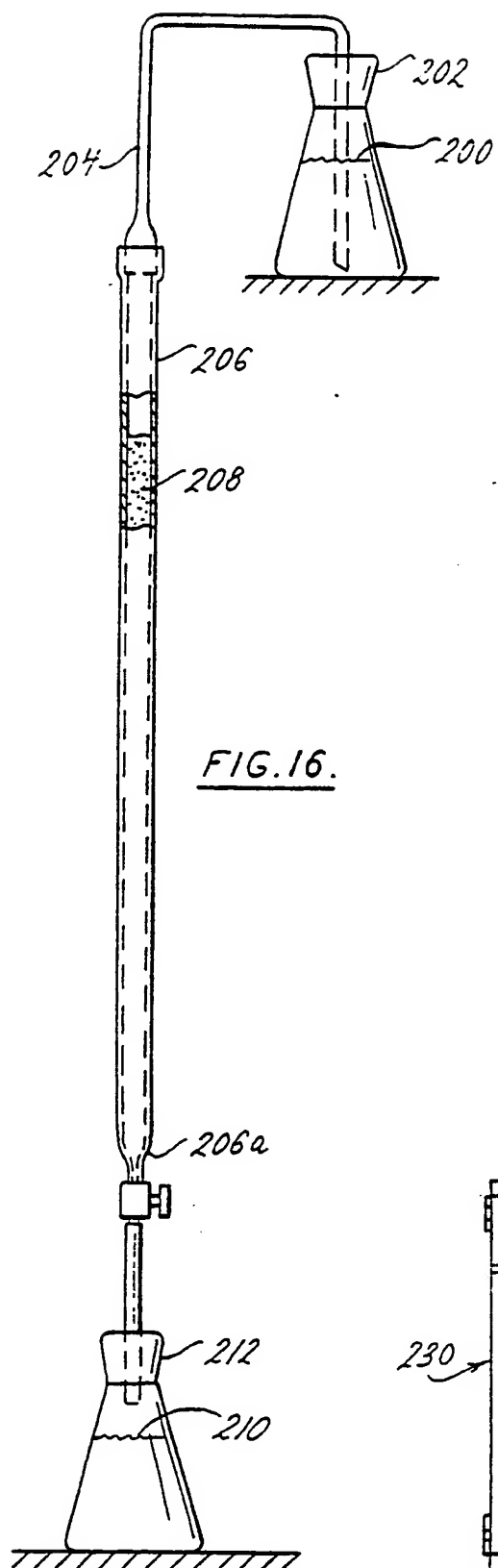


FIG. 16.

FIG. 19.

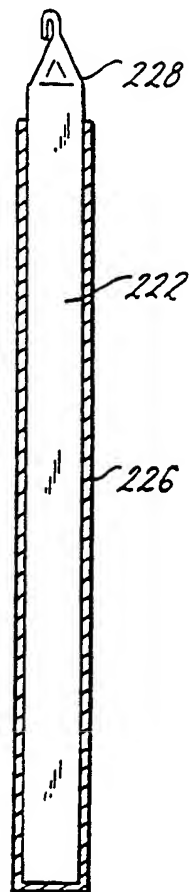


FIG. 21.

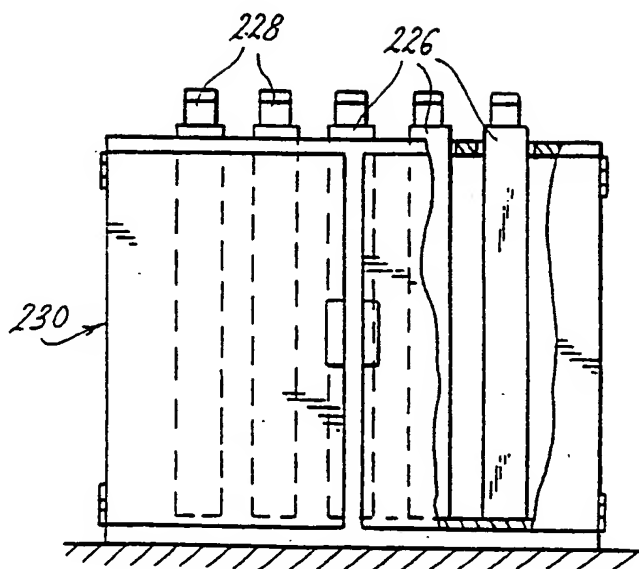
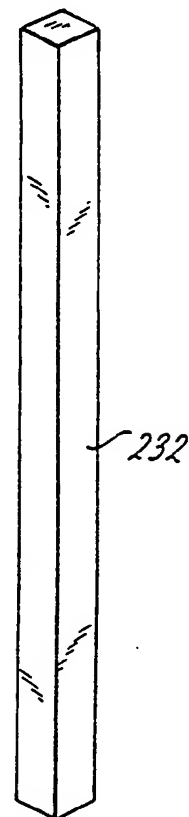


FIG. 20.

**SUBSTITUTE SHEET**



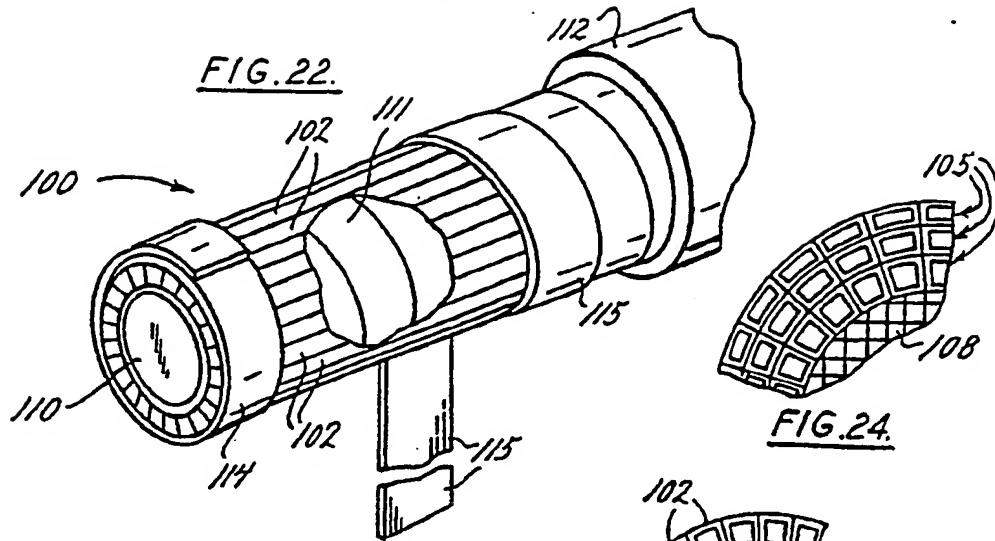


FIG. 25.

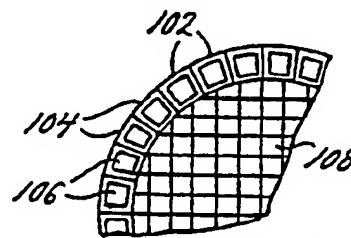
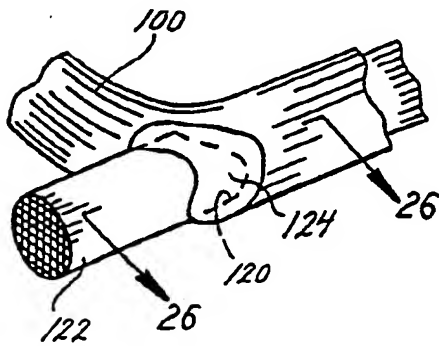


FIG. 23.

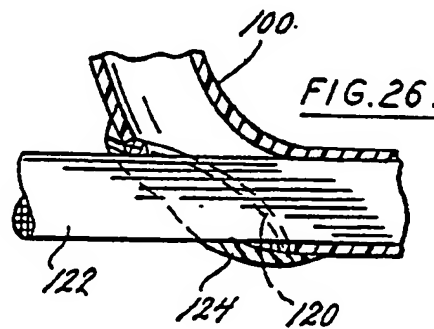


FIG. 26.

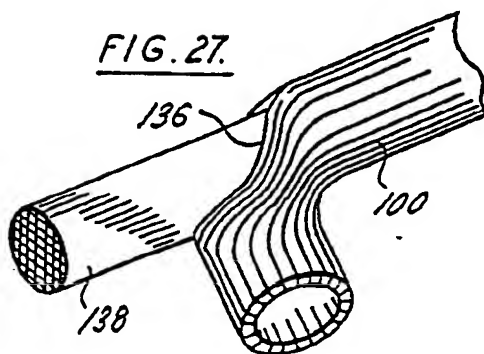


FIG. 27.

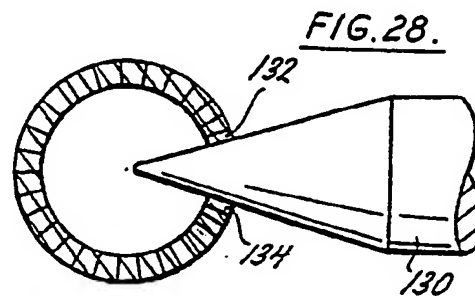


FIG. 28.

# INTERNATIONAL SEARCH REPORT

International Application No. PCT/US91/02404

<b>I. CLASSIFICATION OF SUBJECT MATTER</b> (if several classification symbols apply, indicate all) <sup>6</sup>		
According to International Patent Classification (IPC) or to both National Classification and IPC		
IPC(5): G02B 23/26		
US CL.: 350/96.26		
<b>II. FIELDS SEARCHED</b>		
Minimum Documentation Searched <sup>7</sup>		
Classification System	Classification Symbols	
US	350/96.1, 96.24, 96.25, 96.26	
Documentation Searched other than Minimum Documentation to the Extent that such Documents are Included in the Fields Searched <sup>8</sup>		
<b>III. DOCUMENTS CONSIDERED TO BE RELEVANT <sup>9</sup></b>		
Category <sup>10</sup>	Citation of Document, <sup>11</sup> with indication, where appropriate, of the relevant passages <sup>12</sup>	Relevant to Claim No. <sup>13</sup>
Y	US, A, 3,225,193 (HILTON ET AL.) 21 December 1965 See entire document.	46,61
A	US, A, 3,554,721 (GARDNER) 12 January 1971 See column 2, lines 35-46.	1-3,6,33-35,39 42,52-54,57
X	US, A, 3,580,775 (SIEGMUND) 25 May 1971 See column 2, lines 9-55.	48-51
X	US, A, 3,588,221 (SIEGMUND) 28 June 1971 See column 2, line 46 and column 3, line 6.	48-51
Y	US, A, 4,830,460 (GOLDENBERG) 16 May 1989 See column 10, lines 3-13; column 11, lines 30-44; column 12, lines 18-30; and column 13, lines 53-55	4,5,25-32
Y	US, A, 4,872,740 (TERADA ET AL.) 10 October 1989 See entire document.	1-47
P,Y	US, A, 4,921,326 (WILD ET AL.) 01 May 1990 See column 3, line 42 and column 4, line 2; column 4, lines 46-60.	21-23
<p><sup>10</sup> Special categories of cited documents:</p> <p>"A" document defining the general state of the art which is not considered to be of particular relevance</p> <p>"E" earlier document but published on or after the international filing date</p> <p>"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)</p> <p>"O" document referring to an oral disclosure, use, exhibition or other means</p> <p>"P" document published prior to the international filing date but later than the priority date claimed</p> <p>"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention</p> <p>"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step</p> <p>"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.</p> <p>"&amp;" document member of the same patent family</p>		
<b>IV. CERTIFICATION</b>		
Date of the Actual Completion of the International Search	Date of Mailing of this International Search Report	
02 JULY 1991	18 JUL 1991	
International Searching Authority	Signature of Authorized Officer	
ISA/US	NGUYEN NGOC HO INTERNATIONAL DIVISION JOHN D. LEE	

Form PCT/ISA/210 (second sheet) (Rev.11-87)